

REMARKS

I. Introduction

Receipt is acknowledged of a non-final office action dated February 17, 2004. In the action the examiner rejected claims 4, 9 and 11 as allegedly failing to meet the written description requirement, claims 3-7, 9 and 11 as allegedly non-enabled, and claims 3, 6-7 and 11 as allegedly indefinite. The examiner also rejected claims 3-7, 9 and 11 for non-statutory double patenting, and objected to claims 4-5 and 9 for formality reasons.

Reconsideration of this application is respectfully requested.

II. Status of the Claims

In this response claims 3, 4, 9 and 11 have been amended. Claims 3, 9, and 11 have been amended to state that the polypeptide has “detoxification” activity, rather than “protease inhibitory” activity. Support for this amendment can be found throughout the specification, and on pages 1 and 2 of the application in particular. In addition, claims 3, 9 and 11 have been amended to recite “at least 95% sequence identity” instead of “at least 90% sequence identity” and claim 4 has been amended to recite a polynucleotide “comprising an amino acid sequence of SEQ ID NO: 1.” Support for this amendment can be found throughout the specification, and on page 20 of the specification in particular. Applicants also added new claims 63-66, which are supported by originally filed claim 11 and the specification on pages 8 and 10. Upon entry of these amendments, claims 3-7, 9, 11 and 63-66 will be under examination.

Because the foregoing amendments do not introduce new matter, entry thereof by the Examiner is respectfully requested.

III. Claim Objections

Claims 4-5 and 9 were objected to “as being of improper dependent form for failing to further limit the subject matter of a previous claim.” Office action at 2. In the interest of expediting prosecution, applicants amended claims 4 and 9, thereby rendering this rejection moot.

IV. New Matter

Continuing, the examiner objected to applicants amendment dated December 9, 2003 for allegedly introducing new matter into the present application. In particular, the examiner objected to the phrase “phosphate inhibitory activity” specifically recited in claim 3.

Without acquiescing to the examiner’s rejection, and in the interest of expediting prosecution, claim 3 has been amended to delete this phrase. Amended claim 3 recites “detoxification activity,” which is understood by one of skill in the art to result in the metabolic conversion of a pharmacologically active and often toxic molecule to a pharmacologically less active molecule. Furthermore, a skilled artisan at the time of filing would know what is meant by a detoxification protein. Exemplary support for this amendment can be found on page 1, lines 9-10; and page 2, lines 17-18, of the present specification.

V. Rejection of the Claims Under 35 USC § 112, first paragraph

A. Written Description Rejection

Claims 4, 9 and 11 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to meet the written description requirement. Specifically, the examiner stated that the claims “are directed to a genus of DNA...molecules with either SEQ ID NO: 3 having the limitation of encoding a protein which is 90% identical to the sequence of SEQ ID NO: 1, with no defined function, or a method of making such a protein or any DNA sequence which [is] identical to SEQ ID NO: 3.” Office action at 3-4. The examiner stated that “neither clear

cut guidance, nor even a single example is provided as to what regions/motifs/nucleotides of the sequence(s) are modified without impairing the functionality of the DETX protein in order to create a sequence having 90% identity with respect to SEQ ID NO: 1 or 3.

Applicants respectfully traverse this ground for rejection

**1. The Application Provides Written Description
for the Sequence Encompassed by Claim 4**

Claim 4 recites a polynucleotide encoding a specific sequence (SEQ ID NO: 1), which is provided in the specification. One of skill in the art can readily identify the polynucleotide sequence that encodes a protein identified by a specific SEQ ID number. In fact, one of skill in the art would know which nucleotides can be changed and still encode a particular amino acid. Moreover, the examiner concedes that SEQ ID NO's 1 and 3 are disclosed. *See* office action at 6. Therefore, the written description rejection with respect to claim 4 should be withdrawn.

**2. The Application Provides Written Description for Sequences
that are at Least 90% Identical to the Claimed DETX Sequence**

Likewise, because of the degeneracy in the genetic code, a skilled artisan can alter a nucleic acid sequence encoding DETX without changing the encoded amino acid sequences. *See* specification at 22. Thus, in light of the present specification, a skilled artisan would understand what is meant by a molecule having at least 90% identity with SEQ ID NO: 3.

Moreover, the polypeptides and polynucleotides of claims 9 and 11, respectively, are sufficiently described in the present specification. For example, the claimed invention recites that the polypeptides and fragments thereof possess detoxification activity, which can be readily assayed by techniques known in the art. Indeed, the specification describes an assay that correlates with DETX activity and therefore, can be used to screen sequences that share 90% sequence identity with SEQ ID NO: 1 or 3 and meet the functional requirement of the presently claimed invention. The specification also describes which amino acid substitutions can be made to a nucleotide or amino acid sequence. *See* specification at 8, last full paragraph. Nevertheless, in the interest of expediting prosecution, applicants amended the

claims to recite “at least 95% sequence identity” to SEQ ID NO: 1 or 3. Support for this amendment can be found on page 20, lines 16-18 and lines 32-34 of the present specification.

Accordingly, withdrawal of this ground for rejection is courteously requested.

B. Enablement Rejection

Claims 3-7, 9 and 11 were rejected under 35 U.S.C. § 112, first paragraph, allegedly for non-enablement. The examiner conceded that the specification is “enabling for a polynucleotide of SEQ ID NO: 3, encoding a human detoxification protein (or DETX1) polypeptide of SEQ ID NO: 1,” but asserted that a “polynucleotide having 90% identity to SEQ ID NO: 3 or a polynucleotide encoding a polypeptide having at least 90% sequence identity to the amino acid sequence of SEQ ID NO: 1 [is not enabled].” Office action at 7.

Applicants respectfully traverse this ground for rejection. As stated above, a skilled artisan would know, based on the teachings in the present specification, how to make and use the inventive DETX proteins of the claimed invention. In other words, one of skill in the art would know which modifications can be made to the DETX protein or nucleic acid encoding the protein, and assess functional activity of the protein.

Accordingly, withdrawal of this ground for rejection is courteously requested.

VI. Rejection of Claims Under 35 USC § 112, Second Paragraph

Claims 3, 6-7 and 11 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. In particular, the examiner stated that the phrase “naturally occurring” “contradicts the limitation(s) in the opening phrase of the claims [which recites] ‘isolated.’” Office action at 9. Applicants respectfully traverse this ground for rejection.

Claims 3 and 11 have been amended to delete the recitation of “naturally occurring” for the sole purpose of expediting prosecution of this case.

VII. Rejection of Claims Under 35 USC § 101

Claims 3-7, 9 and 11 were rejected under 35 U.S.C. § 101 as allegedly lacking utility. Specifically, the examiner stated that “[t]he specification does not disclose a specific function of the polypeptides of SEQ ID NO: 1, its relationship to any disease, or any specific real world use.” Office action at 11. Applicants respectfully traverse this ground for rejection.

The examiner has the initial burden of challenging an asserted utility by providing evidence showing that a skilled artisan would reasonably doubt the asserted utility. M.P.E.P. § 2164.08. The examiner has not met this burden.

A. DETX Compositions of the Claimed Invention are Useful and Operative

The present application describes that “DETX appears to play a role in autoimmune/inflammatory disorders, and cell proliferative disorders, including cancer.” Specification at 33. The specification further describes disorders that are associated with decreased DETX expression and how one would achieve increased DETX expression to treat or prevent such disorders. Specification at 33, lines 4-32.

Continuing, the examiner stated that “[e]ven accepting the plausible utility of being a human detoxification protein, one of ordinary skill in the art would not know which compound(s) are detoxified by the polypeptide.” Office action at 11. The USPTO does not require applicants to describe the mechanism by which a given compound acts for a showing of utility. All that is required is that the composition is useful or operative. As discussed above, the present specification describes that the DETX methods and compositions of the present invention can be used to treat or prevent certain disorders. Thus, the utility requirement for the claimed invention has been met.

Accordingly, withdrawal of this ground for rejection is respectfully requested.

VIII. Double Patenting

Claims 3-7, 9 and 11 were rejected under the judicially created doctrine of double patenting over claims 1-13 of U.S. Patent No. 5, 524,819. Applicants respectfully request that this rejection be held in abeyance until the examiner has indicated allowable subject matter.

In view of the foregoing arguments, it is respectfully requested that the present rejections be withdrawn.

CONCLUSION

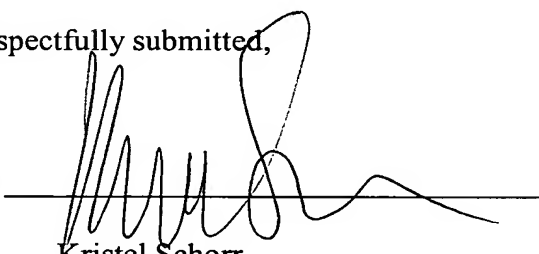
Reconsideration of the present application in view of the foregoing amendments and arguments is kindly requested.

It is respectfully urged that the present application is now in condition for allowance. Early notice to that effect is earnestly solicited.

Examiner Saidha is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application

Respectfully submitted,

By


Kristel Schorr
Patent Agent
Registration No. 55,600

Date May 21, 2004

FOLEY & LARDNER LLP
Customer Number: 22428

22428

PATENT TRADEMARK OFFICE

Telephone: (202) 672-5300

Facsimile: (202) 672-5399